

AMENDED IN SENATE JUNE 11, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 221

Introduced by Assembly Member Portantino
(Coauthors: Assembly Members Fuentes and Jeffries)

February 4, 2009

An act to amend ~~Section~~ Sections 120871 and 120917 of the Health and Safety Code, relating to public health, *and declaring the urgency thereof, to take effect immediately.*

LEGISLATIVE COUNSEL'S DIGEST

AB 221, as amended, Portantino. HIV testing: skin punctures.

Existing law provides for various programs relating to treatment of persons with the human immunodeficiency virus (HIV) and the acquired immunodeficiency syndrome (AIDS).

Existing law requires the State Department of Public Health to authorize the establishment of training programs for counselors for publicly funded HIV testing programs, by community-based, nonprofit organizations meeting prescribed requirements. Existing law requires the participating community-based organizations to follow curriculum content and design for these training programs that is approved by the department.

This bill would require the curriculum content to include training in universal infection control precautions and rapid HIV test proficiency, as specified.

Existing law permits the Office of AIDS in the ~~State Department of Public Health~~ department to participate in a rapid HIV test research program conducted with the federal Centers for Disease Control and Prevention. ~~Under this program,~~

This bill would repeal the authorization for the Office of AIDS to participate in a rapid HIV test research program conducted with the federal Centers for Disease Control and Prevention.

Existing law also authorizes HIV counselors trained by the ~~Office of AIDS in the State Department of Public Health~~ may office to perform skin punctures for purposes of withdrawing blood for HIV test purposes, if the HIV counselor meets prescribed requirements. One of these requirements is that the HIV counselor must hold a valid certification as a phlebotomist technician by the ~~State Department of Public Health~~ department.

This bill would exempt an HIV counselor who is trained by ~~prescribed personnel~~ and in accordance with training requirements established by the department pursuant to the above-mentioned training program curriculum requirements, and who works under a licensed physician and surgeon, from the requirement that he or she hold a valid certification as a phlebotomist technician.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ~~majority~~^{2/3}. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) The United States Centers for Disease Control and
- 4 Prevention estimates that HIV incidence is 40 percent higher than
- 5 previously thought.
- 6 (b) The Office of AIDS in the State Department of Public Health
- 7 estimates that between 30,000 and 40,000 Californians are unaware
- 8 that they are HIV-positive and, therefore, are not receiving
- 9 appropriate HIV treatment and are possibly jeopardizing their own
- 10 health, and that of their sex partners and intravenous drug-using
- 11 partners.
- 12 (c) It is therefore in the interest of the people of the State of
- 13 California to take steps to ensure that people have greater access
- 14 to HIV testing.
- 15 SEC. 2. Section 120871 of the Health and Safety Code is
- 16 amended to read:

120871. (a) The department shall authorize the establishment of training programs throughout the state for counselors for publicly funded HIV testing programs. These training programs shall be conducted by community-based, nonprofit organizations with demonstrated expertise in providing free, anonymous, or confidential HIV testing services. The programs may be offered at flexible times, so as to facilitate the training of volunteer and part-time counselors.

(b) All participating community-based organizations shall follow curriculum content and design approved by the department for training programs administered pursuant to this section. *The curriculum content shall include training in both of the following:*

(1) Universal infection control precautions, consistent with best infection control practices established by the Division of Occupational Safety and Health in the Department of Industrial Relations and the federal Centers for Disease Control and Prevention.

(2) Rapid HIV test proficiency for skin puncture blood tests and oral swab tests.

(c) All counselors trained in programs authorized by this section shall be subject to existing state and local testing and successful completion of training.

(d) All costs associated with training programs administered pursuant to this section shall be absorbed by participating community-based organizations. This section shall not be construed to require or prohibit the funding of any training program administered pursuant to this section by the department, or by any local government administering a training program for HIV counselors.

(e) This section shall not be construed to prohibit or otherwise restrict community-based organizations from participating in existing local training programs.

(f) This section shall not be construed to certify an HIV counselor as a phlebotomy technician or a limited phlebotomy technician, or to fulfill any requirements for certification as a phlebotomy technician or a limited phlebotomy technician, unless the HIV counselor has otherwise satisfied the certification requirements imposed pursuant to Section 1246 of the Business and Professions Code.

1 ~~SEC. 2.~~

2 ~~SEC. 3.~~ Section 120917 of the Health and Safety Code is
3 amended to read:

4 ~~120917. (a) The department, through its Office of AIDS and~~
5 ~~the authorized agents of the office, may participate in a rapid~~
6 ~~human immunodeficiency virus test research program conducted~~
7 ~~with the federal Centers for Disease Control and Prevention,~~
8 ~~involving innovative HIV testing and counseling programs. Under~~
9 ~~the rapid HIV test research program, as authorized by this section,~~
10 ~~the department may do the following:~~

11 ~~(1) Perform and report clinical test results using a rapid HIV~~
12 ~~test for diagnosis, prior to test approval by the federal Food and~~
13 ~~Drug Administration (FDA). However, test performance and~~
14 ~~reporting shall only be done to the extent allowed under that~~
15 ~~device's investigational approval by the FDA and pursuant to a~~
16 ~~California Health and Human Services Agency Institutional Review~~
17 ~~Board-approved research protocol.~~

18 ~~(2) Use a second independent HIV test to confirm initially~~
19 ~~reactive test results to the extent allowed under the investigational~~
20 ~~approval by the FDA. All rapid tests shall be confirmed using~~
21 ~~technology approved by the federal Food and Drug Administration.~~
22 ~~If the results from this confirmatory testing differ from the results~~
23 ~~of the rapid test, the subject shall be notified. No subject shall~~
24 ~~participate in the research protocol who does not provide~~
25 ~~appropriate contact information.~~

26 ~~(b)~~

27 ~~120917. (a)~~ An HIV counselor who is trained by the Office
28 of AIDS and working in an HIV counseling and testing site funded
29 by the department through a local health jurisdiction, or its agents,
30 may do all of the following:

31 (1) Perform any HIV test that is classified as waived under the
32 federal Clinical Laboratory Improvement Act (CLIA) (42 U.S.C.
33 Sec. 263a and following) if all of the following conditions exist:

34 (A) The performance of the HIV test meets the requirements of
35 CLIA and, subject to subparagraph (B), Chapter 3 (commencing
36 with Section 1200) of Division 2 of the Business and Professions
37 Code.

38 (B) Notwithstanding Section 1246 of the Business and
39 Professions Code, an HIV counselor may perform skin punctures
40 for the purpose of withdrawing blood for HIV testing, upon specific

1 authorization from a licensed physician and surgeon, provided that
2 the person meets both of the following requirements:

3 (i) He or she works under the direction of a licensed physician
4 and surgeon.

5 (ii) He or she has been trained in accordance with training
6 requirements established by the department, ~~by a licensed physician~~
7 ~~and surgeon, or by a licensed clinical laboratory scientist or~~
8 ~~bioanalyst in the proper procedures to be employed when~~
9 ~~conducting the skin puncture, and has a statement signed by the~~
10 ~~instructing physician and surgeon, scientist, or bioanalyst that the~~
11 ~~training has been successfully completed. pursuant to subdivision~~
12 ~~(b) of Section 120871. An HIV counselor who has been certified~~
13 ~~using a curriculum pursuant to subdivision (b) of Section 120871~~
14 ~~prior to the inclusion of the curriculum content required in~~
15 ~~paragraphs (1) and (2) of that subdivision and who will administer~~
16 ~~rapid HIV skin puncture tests shall obtain training in the~~
17 ~~curriculum content required by those paragraphs within two years~~
18 ~~of the date that the department approves a curriculum that meets~~
19 ~~the requirements of those paragraphs. The HIV counselor shall~~
20 ~~not, unless also certified as a limited phlebotomist technician,~~
21 ~~perform a skin puncture pursuant to this section until he or she~~
22 ~~has completed the training for the new curriculum content.~~

23 (C) The person performing the HIV test meets the requirements
24 for the performance of waived laboratory testing pursuant to
25 subdivision (a) of Section 1206.5 of the Business and Professions
26 Code. For purposes of this subdivision and subdivision (a) of
27 Section 1206.5 of the Business and Professions Code, an HIV
28 counselor trained by the Office of AIDS shall be “other health care
29 personnel providing direct patient care” as referred to in paragraph
30 (12) of subdivision (a) of Section 1206.5 of the Business and
31 Professions Code.

32 (D) The patient is informed that the preliminary result of the
33 test is indicative of the likelihood of HIV infection and that the
34 result must be confirmed by an additional more specific test, or,
35 if approved by the ~~federal Food and Drug Administration~~ *FDA* for
36 that purpose, a second different rapid HIV test. Nothing in this
37 subdivision shall be construed to allow an HIV counselor trained
38 by the Office of AIDS to perform any HIV test that is not classified
39 as waived under the CLIA.

(2) Notwithstanding Sections 1246.5 and 2053 of the Business and Professions Code, order and report HIV test results from tests performed pursuant to paragraph (1) to patients without authorization from a licensed health care professional or his or her authorized representative. Patients with indeterminate or positive test results from tests performed pursuant to paragraph (1) shall be referred to a licensed health care provider whose scope of practice includes the authority to refer patients for laboratory testing for further evaluation.

~~(e)~~

(b) Notwithstanding any other provision of law, an HIV counselor acting in accordance with this section who successfully completes the HIV counselor training shall be deemed to have demonstrated sufficient literacy and comprehension to advance to the limited phlebotomy technician training and may substitute successful completion of the HIV counselor curriculum for the requirement for a high school diploma or General Education Development (GED) equivalent for a limited phlebotomy technician, as defined in Section 1029.116 of Title 17 of the California Code of Regulations pursuant to Section 1246 of the Business and Professions Code.

~~(d)~~

(c) An HIV counselor who meets the requirements of this section with respect to performing any HIV test that is classified as waived under the CLIA may not perform any other test unless that person meets the statutory and regulatory requirements for performing that other test.

SEC. 4. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

Because HIV screening is so critical to containing the AIDS epidemic, and therefore, persons who can administer rapid HIV testing must be employed as soon as possible, it is necessary that this act go into immediate effect.